510(k) Summary
Liquichek Pediatric Control

K130963

1.0 **Submitter**

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MAY 0 6 2013

Contact Person

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Date of Summary Preparation

April 2, 2013

2.0 **Device Identification**

Product Trade Name:	Liquichek Pediatric Control
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classifications:	Class I, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek Pediatric Control
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K872227

4.0 **Description of Device**

Liquichek Pediatric Control is prepared from bovine serum with added chemicals, therapeutic drugs, preservatives and stabilizers. The control is provided in liquid form for convenience.

5.0 **Value Assignment**

The mean values and the corresponding ±3SD ranges printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

6.0 Intended Use

Liquichek Pediatric Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

7.0 Comparison of the new device with the Predicate Device

Liquichek Pediatric Control claims substantial equivalence to the Liquichek Pediatric Control currently in commercial distribution (K872227). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table 1: Similarities and Differences Between the New and Predicate Device

Characteristics	Liquichek Pediatric Control (New Device)	Liquichek Pediatric Control (Predicate Device, K872227)
	Similarities	
Intended Use	This product is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	This product is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Liquid	Liquid
Matrix	Bovine Serum	Bovine Serum
Thawed & Opened Stability	14 days at 2 to 8°C	14 days at 2 to 8°C
	Differences	
Fill Volume	2.5 mL	4 mL
Thawed and Unopened Stability	45 days at 2 to 8°C or on-board Dimension Vista at 2 to 8°C	3 months at 2 to 8°C
Storage Unopened (Shelf life)	At -20 to -50°C until the expiration date	At -20 to -70°C until the expiration date
Analytes	**Contains:** Bilirubin, Direct Bilirubin, Total Caffeine Calcium Chloride Glucose Magnesium Potassium Sodium Theophylline **Does not contain:** Bilirubin, Indirect Bilirubin, Neonatal Phenylalanine	**Contains:** Bilirubin, Direct Bilirubin, Indirect Bilirubin, Neonatal Bilirubin, Total Caffeine Calcium Chloride Glucose Magnesium Phenylalanine Potassium Sodium Theophylline

8.0 Statement of Supporting Data

Real-time stability studies were conducted to establish the thawed stability claims (opened-vial and unopened-vial). Accelerated stability studies were conducted to establish the shelf-life claims at -20 to -50°C. Product claims are as follows:

Thawed and Opened Stability:	14 days at 2 to 8°C
Thawed and Unopened Stability:	45 days at 2 to 8°C
Shelf Life Stability:	3 years at -20 to -50°C

9.0 Conclusion

Based on the performance characteristics indicated above, the Bio-Rad Liquichek Pediatric Control is substantially equivalent to the predicate device, K872227.

All supporting data are retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 6, 2013

Bio-Rad Laboratories
C/O Ms. Suzanne Parsons
9500 Jeronimo Road
IRVINE CA 92618

Re: K130963
Trade/Device Name: Liquichek Pediatric Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: I, reserved
Product Code: JJY
Dated: April 02, 2013
Received: April 08, 2013

Dear Ms. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130963

Device Name: Liquichek Pediatric Control

Liquichek Pediatric Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

Prescription Use ____X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k): __k130963_